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Safety of Percutaneous Dilatational Tracheotomy in Patients on Dual Antiplatelet Therapy and Anticoagulation

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Objective: Percutaneous dilatational tracheotomy has become a routine procedure in ICUs. However, given the high and steadily growing number of patients receiving anticoagulation, dual antiplatelet therapy, or even a combination of both (also known as "triple therapy"), there are concerns about the safety of the procedure, in particular for critically ill patients with a high risk of bleeding. In this retrospective study, we investigated whether percutaneous dilatational tracheotomy in this high-risk population was associated with elevated procedural complications.

Design: Retrospective single-center study with analysis of all percutaneous dilatational tracheotomies performed in our cardiac ICU from January 2018 to May 2019.

Setting: Munich university hospital's cardiac ICU.

Patients and Interventions: A total of 34 patients who underwent percutaneous dilatational tracheotomy according to Ciaglia technique with accompanying bronchoscopy in our cardiac ICU from January 2018 to May 2019 were included. Patients were stratified into clinically relevant risk groups based on anticoagulation and antiplatelet therapy considering standard laboratory coagulation parameters, that is, activated partial thromboplastin time, international normalized ratio, and platelet count with differentiated analysis of procedure-related complications in each risk group until hospital discharge.

Measurements and Main Results: A total of 34 patients who underwent percutaneous dilatational tracheotomy were included and assigned to five clinically relevant treatment groups: IV unfractionated heparin (prophylactic dosage) ($n = 4$), IV unfractionated heparin (therapeutic dosage) ($n = 4$), aspirin and IV unfractionated heparin (therapeutic dosage) ($n = 7$), dual antiplatelet therapy with IV unfractionated heparin (prophylactic dosage) ($n = 5$), and dual antiplatelet therapy with IV unfractionated heparin (therapeutic dosage) ($n = 14$). Three bleedings without surgical intervention or blood transfusion were documented in the whole cohort, but no single bleeding did occur in the triple therapy group. These were exclusively caused by skin bleedings at the immediate puncture site—each of which could be easily treated with one or two single stitches. There were no severe bleeding complications or potentially life-threatening procedure-related complications. Additionally, the rate of complications in patients with elevated body mass index was not increased.

Conclusions: Bronchoscopy-guided percutaneous dilatational tracheotomy according to Ciaglia technique with careful consideration of all potential indications and contraindications may be a safe and low-complication procedure for airway management, even in patients receiving dual antiplatelet therapy and therapeutic anticoagulation simultaneously in our cohort with a high risk of bleeding.

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During the last 2 decades, percutaneous dilatational tracheotomy (PDT) has become a well-established procedure for mid- and long-term ventilated ICU patients (1). The main indications are upper airway obstruction, respirator weaning failure, long-term mechanical ventilation based on neurologic disorders, and securing a patent airway to maintain proper expectoration of bronchial secretion (2, 3). PDT is considered the standard of care to prevent complications caused by long-term translaryngeal intubation like irreversible injury of the vocal cords, laryngeal mucosal erosions, laryngeal scaring and stenosis, as well as injury of the recurrent laryngeal nerve or other irreversible damage to anatomical structures of the upper respiratory tract (4, 5).

The most common percutaneous dilatational technique first described by Ciaglia et al (6) is usually performed at the bedside (6, 7). In this case, the access is dilated in several steps after puncture of the trachea and insertion of a Seldinger wire (Angiokard, Friedeburg, Germany) until the tracheal cannula is finally placed. Randomized trials have shown a lower occurrence rate of bleeding and infections associated with PDT in comparison to open surgical tracheotomy (8–11). In recent years, however, the ICU patient population—especially in cardiovascular ICUs—has changed in such a way that the proportion of patients receiving dual platelet inhibition or even triple therapy, that is, patients receiving both dual platelet inhibition and therapeutic anticoagulation, has increased significantly and will continue to increase in light of an aging population. Furthermore, many critically ill patients suffer from thrombocytopenia or coagulation disorders due to severity of illness, sepsis, or organ dysfunctions (12). Mallick and Bodenham (13) as well as Klotz et al (14) have recently pointed out that coagulation disorders may be a relative contraindication for PDT. Against this background, our retrospective single-center study aims to investigate to what extent PDT can still be regarded as a safe procedure for ICU patients even in the steadily growing group of patients with a high risk of bleeding and to analyze possible complications in different risk groups, also depending on supposedly relevant cofactors, such as the body mass index (BMI).

METHODS

Study Design and Patient Selection

A retrospective single-center cohort analysis was performed on all patients admitted to Munich university hospital's cardiac ICU who underwent PDT under at least prophylactic anticoagulation between January 2018 and May 2019. The indication for PDT in all cases was an expected prolonged respirator-dependent ventilation period of 7 days and above. All data were taken from the central clinical database and detailed documentation of each patient with subsequent data anonymization. Patients were stratified into clinically relevant risk groups based on anticoagulation and antiplatelet therapy considering standard laboratory coagulation parameters, that is, activated partial thromboplastin time (aPTT), international normalized ratio (INR), and platelet count with differentiated analysis of procedure-related complications. The study was designed, performed, and reported using approaches consistent with the recommendations of this Journal, approved by the local ethics committee and conducted in accordance with the institutional and national guidelines.

Percutaneous Dilatational Technique

All patients included in this study underwent PDT according to Ciaglia technique with accompanying bronchoscopy (6, 7) as standard bedside procedure on our ICU. In doing so, an experienced senior ICU consultant team comprising 2 experienced interventionalists—performing at least 20 PDTs as an operator/bronchoscopy team per year—dilates the tracheal access in several steps after median puncture of the trachea below the second or third tracheal clasp under bronchoscopic visualization and insertion of a Seldinger wire (15, 16). Previously a Doppler ultrasound examination is used routinely to ensure that no blood vessels run under the intended puncture site. The Seldinger guidewire is used for bougienage with the dilator (Ciaglia Blue Rhino Set; Cook Medical, Bloomington, IN). Subsequently, the tracheal cannula (size, 9 mm) is inserted by an introducer and connected to the respiratory system (**Fig. 1**). To prevent bleeding from the puncture site, two single-head sutures are placed left and right of the tracheal cannula. Before and throughout PDT, patients are ventilated with F_{IO_2} equals to 1.0 (biphasic positive airway pressure ventilation). Finally, a bronchoscopic position control of the tracheal cannula and a postinterventional rule out of pneumothorax by chest radiograph are performed. For anesthesia, all patients received fentanyl (20–50 μg/kg) or sufentanil (8–20 μg/kg), propofol (1.5–2.5 mg/kg), and cisatracurium as short-acting muscle relaxant (0.15 mg/kg). Anticoagulation with unfractionated heparin was stopped 4 hours before each PDT and restarted 4 hours after the procedure.

Blood Sampling and Platelet Function Testing

Whole blood for testing adenosine diphosphate-induced platelet aggregation on the Multiplate analyzer (Roche, Reinach, Switzerland) was obtained under steady-state conditions by venipuncture. Details of this method have been reported previously (16). Aggregation was quantified as units of platelet aggregation. High platelet reactivity (HPR) and low platelet reactivity (LPR) were defined according to consensus definition documents and according to the established cut-off values with HPR greater than or equal to 46 U and LPR less than or equal to 18 U on the Multiplate analyzer (Roche) (17).

Statistical Analysis

Statistical analysis was carried out using GraphPad Prism (version 7.0; GraphPad Software, San Diego, CA). Kolmogorov-Smirnov test, D'Agostino-Pearson omnibus test, q-q-plots, and histograms were used to test normality of data distribution. In addition to normality, also equal variance was tested. Normally distributed data were tested using analysis of variance; non-normally distributed data using the Kruskal-Wallis test. Data are presented as mean ± SD and mean difference with 95% CIs. *p* values less than 0.05 were considered significant.

RESULTS

Patient Baseline Characteristics

Depending on anticoagulant treatment regimens under consideration of antiplatelet therapy, a total of 34 patients were included and assigned to five clinically relevant treatment groups with a priori

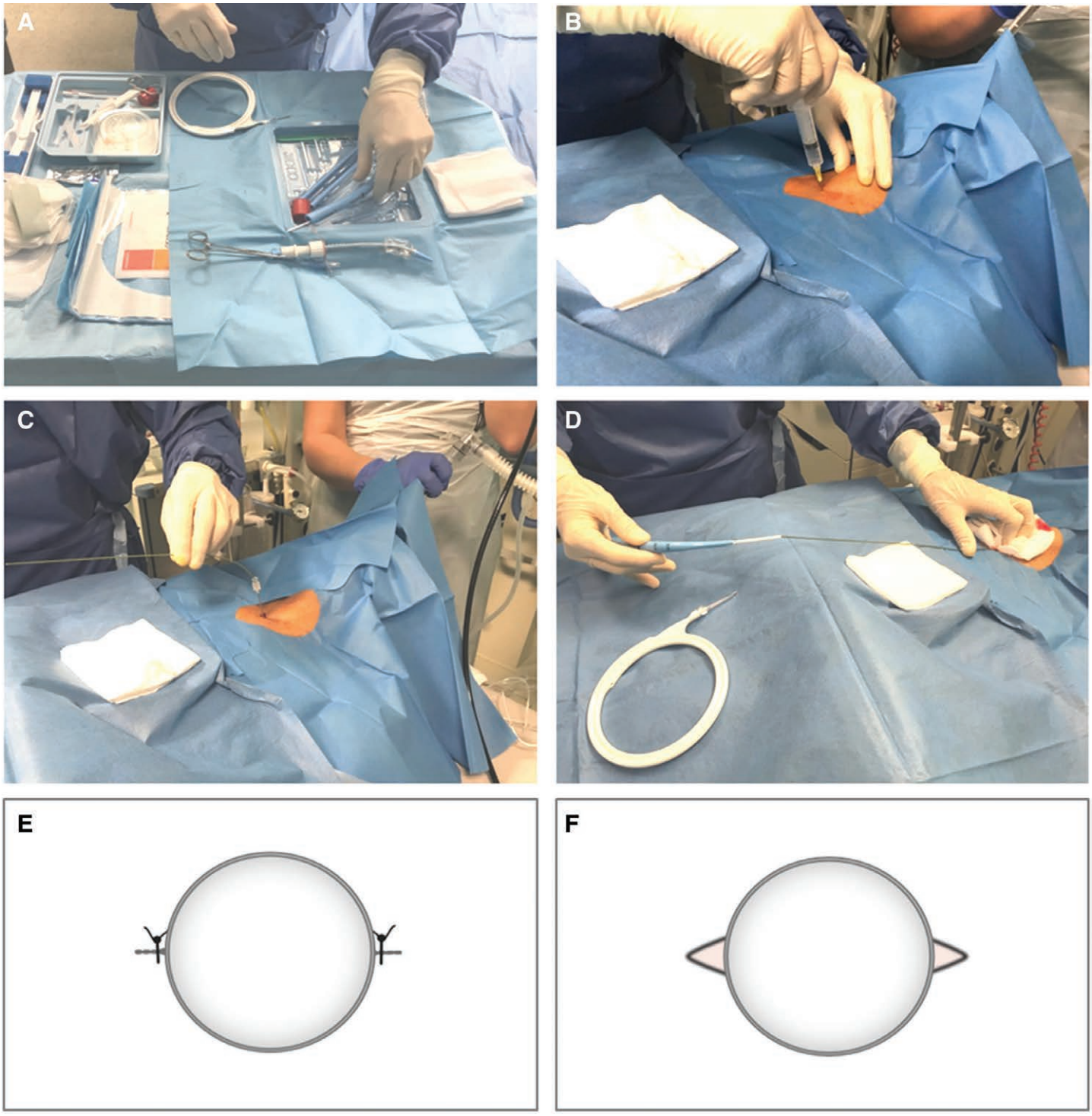

Figure 1. Percutaneous dilatational tracheotomy according to Ciaglia technique (**A**) with accompanying bronchoscopy: Doppler ultrasound examination used to ensure that no blood vessels run under the intended puncture site. Median puncture of the trachea below the second or third tracheal clasp under bronchoscopic visualization (**B**) and insertion of a Seldinger wire (**C**). The Seldinger guidewire is used for bougienage with the dilator (Ciaglia Blue Rhino Set; Cook Medical) (**D**). Subsequently, the tracheal cannula (size: 9 mm) is inserted by means of an introducer and connected to the respiratory system. Final bronchoscopic position control of the tracheal cannula and postinterventional rule out of pneumothorax by chest radiograph. Two single-head sutures on the left and right of the tracheal cannula to prevent bleeding from the puncture site (**E** and **F**).

different risks of bleeding: IV unfractionated heparin (prophylactic dosage) (I), IV unfractionated heparin (therapeutic dosage) (II), aspirin (100 mg/d) and IV unfractionated heparin (therapeutic dosage) (III), dual antiplatelet therapy (DAPT) including aspirin (100 mg/d), and a $P2Y_{12}$ receptor antagonist, antiplatelet agent receptor inhibitor, that is, clopidogrel (75 mg/d), prasugrel (10 mg/d), or ticagrelor (90 mg bid), with IV unfractionated heparin (prophylactic dosage) (IV) and DAPT with IV unfractionated heparin (therapeutic dosage), also known as "triple therapy" (V). Detailed clinical information regarding different treatment groups can be found in **Table 1**.

TABLE 1. Baseline Characteristics of Different Treatment Groups With a Total of 34 Patients Included Between January 2018 and May 2019 in Munich University Hospital's Cardiac ICU

Treatment Group	Heparin (Prophylactic Dosage) (I) (*n* = 4)	Heparin (Therapeutic Dosage) (II) (*n* = 4)	Aspirin and Heparin (Therapeutic Dosage) (III) (*n* = 7)	DAPT With Heparin (Prophylactic Dosage) (IV) (*n* = 5)	DAPT With Heparin (Therapeutic Dosage) (V) (*n* = 14)	Overall (*n* = 34)
Age (yr)	39.75 ± 12.61	50.25 ± 17.76	69.71 ± 6.52	53.60 ± 11.97	63.75 ± 13.68	59 ± 15.29
Gender (male)	4	3	5	3	13	28
Body mass index (kg/m^2)	28.25 ± 2.50	22.50 ± 2.08	23.43 ± 3.95	22.60 ± 2.41	25.93 ± 4.32	24.79 ± 3.95
Tracheotomy technique	PDT	PDT	PDT	PDT	PDT	PDT
Size of cannula (mm)	9	9	9	9	9	9
Days after intubation	7.5 ± 1.5	8.0 ± 2.5	7.5 ± 2.0	7.0 ± 1.5	8.0 ± 2.5	7.0 ± 2.0
Reason for hospitalization	ARDS (2), SS (1), CS (1)	COPD (1), endocarditis (1), CS (2)	ARDS (1), DHF (2), SS (1), CS (2), HS (1)	STEMI (2), NSTEMI (2), CS (1)	STEMI (3), NSTEMI (2), SS (1), CS (8)	ARDS (3), SS (3), CS (14), HS (1) COPD (1), endocarditis (1), DHF (2), STEMI (5), NSTEMI (4)
Hypertension	3	2	5	2	12	24
Diabetes mellitus	1	0	1	2	5	9
Current smoker	0	2	2	1	3	8
Chronic kidney disease	0	0	2	0	3	5
Previous stroke	0	0	1	0	1	2
Atrial fibrillation	0	3	4	0	9	16
Heparin	Prophylactic (4)	Therapeutic (4)	Therapeutic (7)	Prophylactic (5)	Therapeutic (14)	Prophylactic (9) Therapeutic (25)
Aspirin	0	0	7	5	14	28
$P2Y_{12}$ receptor antagonist, antiplatelet agent inhibitors	0	0	0	5	14	21
Creatinine (mg/dL)	2.0 ± 0.48	0.98 ± 0.63	1.51 ± 0.45	1.22 ± 0.90	1.39 ± 0.77	1.41 ± 0.71
Hemoglobin (g/dL)	9.40 ± 0.68	10.45 ± 1.89	9.86 ± 1.21	10.26 ± 1.52	9.55 ± 1.10	9.81 ± 1.23
Platelet count (G/L)	139.25 ± 74.22	176.75 ± 29.98	178 ± 153.08	224.80 ± 66.91	260.36 ± 147.48	214.09 ± 126.51
Quick (%)	83 ± 24.26	84.74 ± 15.78	74.43 ± 9.22	94.60 ± 16.38	69.64 ± 20.98	77.65 ± 19.49
International normalized ratio	1.18 ± 0.21	1.13 ± 0.15	1.20 ± 0.10	1.04 ± 0.11	1.34 ± 0.39	1.22 ± 0.28
Activated partial thromboplastin time (s)	31.75 ± 7.63	44.25 ± 12.92	51.29 ± 14.23	28 ± 5.24	53.43 ± 13.39	45.62 ± 15.31

ARDS = acute respiratory distress syndrome, COPD = chronic obstructive pulmonary disease, CS = cardiogenic shock, DAPT = dual antiplatelet therapy, DHF = decompensated heart failure, HS = hemorrhagic shock, NSTEMI = non-ST segment elevation myocardial infarction, PDT = percutaneous dilatational tracheotomy, SS = septic shock, STEMI = ST-elevation myocardial infarction.

All displayed laboratory values were recorded on the day of the PDT. Treatment group I: IV unfractionated heparin (prophylactic dosage); II: IV unfractionated heparin (therapeutic dosage), III: aspirin (100 mg/d) and IV unfractionated heparin (therapeutic dosage); IV: DAPT including aspirin (100 mg/d) and a $P2Y_{12}$ receptor antagonist, antiplatelet agent receptor inhibitor, i.e., clopidogrel (75 mg/d), prasugrel (10 mg/d), or ticagrelor (90 mg bid), with IV unfractionated heparin (prophylactic dosage); V: DAPT with IV unfractionated heparin (therapeutic dosage).

Patients included in this study were distributed among mentioned treatment groups as follows: I ($n = 4$), II ($n = 4$), III ($n = 7$), IV ($n = 5$), and V ($n = 14$), accordingly 41% of them underwent PDT on triple therapy, 15% with DAPT and IV unfractionated heparin (prophylactic dosage), 20% with aspirin and IV unfractionated heparin (therapeutic dosage), and 12% with heparin in therapeutic or prophylactic dosage, respectively. The baseline characteristics of all groups are summarized in Table 1. The overall mean age was 59 ± 15.29, with 82% being male. Hemoglobin levels at the day of PDT were 9.81 ± 1.23 g/dL, platelet counts 214.09 ± 126.51 G/L, quick values 77.65% ± 19.49%, INR values 1.22 ± 0.28, and aPTT values 45.61 ± 15.31 seconds. PDT was performed 7.0 ± 2.0 days after primary intubation. The most frequent reasons for the hospital stay were cardiogenic shock, ST-elevation myocardial infarction, and non-ST segment elevation myocardial infarction. As expected, mean aPTT values were highest in treatment groups II, III, and V. Sufficient platelet inhibition on $P2Y_{12}$ receptor inhibitors could be assured in all patients after myocardial infarction or after percutaneous coronary intervention using whole blood impedance aggregometry measured on Multiplate analyzer (Roche) as previously described (17).

Association Between Treatment Group and Complications

As shown in **Table 2**, the overall complication rate across all treatment groups was low. In particular, life-threatening complications and those associated with long-term patient injury did not occur during the procedure. Despite the increased risk of bleeding due to the treatment regimens included in this study, no intraprocedural bleeding was recorded. A total of three postprocedural bleeding events in group I (1), III (1), and IV (1) were mild and clinically nonrelevant bleeding in the area of the cannula incision, all of which were easily controlled with two single-head sutures on the left and right of the tracheal cannula (Fig. 1, *E* and *F*). PDT-related blood transfusions or surgical intervention were not required in any case. No single relevant bleeding was documented in the triple therapy group.

An accidental tube dislocation during PDT procedure occurred in two patients, all of which could be easily handled via bronchoscopically controlled tube repositioning without relevant oxygen desaturation. Fracture of tracheal cartilage occurred in four cases. However, the affected cartilage was twice only slightly dislocated and this was never associated with relevant airway obstruction, bleeding, or wound healing disorders. All other complications noted in Table 2, which are relevant when estimating the safety of a procedure such as PDT, did not occur at all. In particular, there were no significant differences between analyzed treatment groups. Overall, 44% of patients had an elevated BMI value (BMI ≥ 25 kg/m^2), and interestingly, even in patients with comparatively high BMI values, no significant increase in complications was observed (Table 3).

DISCUSSION

The feasibility and safety of PDT in mid- and long-term ventilated patients of cardiac ICUs have not been shown in a high

TABLE 2. Complications During and After Percutaneous Dilatational Tracheotomy Differentiated by Treatment Group

Complication	I ($n = 4$)	II ($n = 4$)	III ($n = 7$)	IV ($n = 5$)	V ($n = 14$)	Overall (%)	*p*
Intraprocedural bleeding	0	0	0	0	0	0	NS
Postprocedural bleeding	1	0	1	1	0	3 (8.8)	NS
Accidental cannula dislocation	0	0	0	0	0	0	NS
Accidental tubes dislocation	0	0	0	0	2	2 (5.9)	NS
Tracheocutaneous fistula	0	0	0	0	0	0	NS
Fracture of tracheal cartilage	0	0	3	0	1	4 (11.8)	NS
Pneumothorax	0	0	0	0	0	0	NS
Infection	0	0	0	0	0	0	NS
Wound healing disorder	0	0	0	0	0	0	NS
Granulation at the tracheostoma	0	0	0	0	0	0	NS
O_2 desaturation	0	0	0	0	0	0	NS
Hypotension	0	0	0	0	0	0	NS
Cardiac arrhythmia	0	0	0	0	0	0	NS
Resuscitation	0	0	0	0	0	0	NS
Death	0	0	0	0	0	0	NS
Need for transfusion	0	0	0	0	0	0	NS
Need for surgical intervention	0	0	0	0	0	0	NS

NS = nonsignificant.

p values < 0.05 were considered as significant.

TABLE 3. Complications During and After Percutaneous Dilatational Tracheotomy Differentiated by Body Mass Index

Body Mass Index (kg/m²)	16–19 (*n* = 1)	20–24 (*n* = 18)	25–30 (*n* = 10)	31–40 (*n* = 5)	*p*
Intraprocedural bleeding	0	0	0	0	NS
Postprocedural bleeding	0	2	1	0	NS
Accidental cannula dislocation	0	0	0	0	NS
Accidental tubes dislocation	0	1	1	0	NS
Tracheocutaneous fistula	0	0	0	0	NS
Fracture of tracheal cartilage	1	1	1	1	NS
Pneumothorax	0	0	0	0	NS
Infection	0	0	0	0	NS
Wound healing disorder	0	0	0	0	NS
Granulation at the tracheostoma	0	0	0	0	NS
O_2 desaturation	0	0	0	0	NS
Hypotension	0	0	0	0	NS
Cardiac arrhythmia	0	0	0	0	NS
Resuscitation	0	0	0	0	NS
Death	0	0	0	0	NS
Need for transfusion	0	0	0	0	NS
Need for surgical intervention	0	0	0	0	NS

NS = nonsignificant.
p values < 0.05 were considered as significant.

bleeding–risk cohort because DAPT and anticoagulation are considered as relative contraindications to PDT. Therefore, the present study analyzed procedure-related complications during and after PDT on a single cardiac ICU in 34 consecutive procedures including patients with high bleeding risk. We show here that PDT can safely be performed in this cohort with a very low-complication rate. This is a remarkable finding in light of 41% of patients undergoing PDT on triple therapy with an inherently high risk of bleeding and associated complications. Overall, no case of death was directly attributed to the PDT procedure. Interestingly, the clinical practice showed that mild bleeding in the area of the cannula incision can be easily controlled and even completely prevented with the suture technique shown in **Fig. 1, *E*** and ***F***. For this reason, this technique may be considered to be routinely used in all PDTs.

Our study represents an important addition to the safety analyzes in current literature, which could already show that the risk of bleeding is lower with PDT compared with surgical tracheotomy (9, 15, 18, 19). There are few prior small studies evaluating the safety of PDT among patients receiving DAPT or anticoagulation (20, 21). For example, Nam et al (21) have already shown in a single-center study that PDT performed in critically ill patients taking antiplatelet agents is a feasible procedure and might be performed without additional bleeding complications, keeping in mind that only 18% of patients included in their study received antiplatelet therapy and patients receiving triple therapy were not explicitly identified. In another single-center study by Pasin et al (20), PDT was not associated with higher bleeding complications in critically ill patients treated with anticoagulant therapies. However, none of the patients included received triple therapy, although 72% of patients received anticoagulation. Our study is the first including such a high proportion of patients with DAPT and IV unfractionated heparin in therapeutic dosage, which—in such numbers—can only be found on cardiac ICUs.

Based on the present study, the use of PDT according to Ciaglia technique, if properly indicated, may be recommended as a safe method of securing the airway, even in patients with an increased risk of bleeding due to anticoagulation, DAPT, or a combination of both and resulting impairment of coagulation. Neither DAPT nor triple therapy were statistically significant risk factors for bleeding or any other complications in our study. This is all the more satisfying as PDT is associated with a number of well-documented benefits in current literature: improved patient comfort, improvement of oral hygiene and nurse care, reduced need for sedation and analgesia, spontaneous closure of the wound after decannulation and barely visible scar, shortened weaning period from the respirator, as well as overall shortened ICU stay (1, 22–24). In addition, the use of viscoelastic tests of hemostasis, for example, rotation thromboelastometry (ROTEM) analysis—which was not routinely used in our study—may even further reduce the risk of bleeding complications. For example, Durila et al (22) suggested that surgical tracheostomy can be performed without bleeding complications in case of normal thromboelastometry results, calculated by ROTEM analysis, despite increased INR. Future studies will have to show to what extent that

could also be transferable to PDT. Irrespective of this, a systematic registration of possible procedural risk factors is indispensable in order to increase the awareness and readiness for optimal handling of complications and to enable further risk factor assessments.

Besides DAPT and anticoagulation, obesity has been considered as risk factor for complications, as shown in the study published by Kost et al (3). The author reported a complication rate of 15% in patients with a BMI greater than or equal to 30, compared with 8% in patients with BMI less than 30. We could not reproduce this result as we did not find a significant increase in procedural complications in patients with comparatively high BMI values in accordance with more recent studies, such as that of Rosseland et al (1). Based on our findings, PDT may be performed safely in obese patients and obesity may not be regarded as a general contraindication for PDT. However, ICU consultants, as already pointed out by Rosseland et al (1), should pay attention to the anatomical challenge caused by an increased amount of pretracheal tissue as well as to the physiologic derangements that may occur during airway management in this patient group (1).

The retrospective single-center design is a limitation of our study because findings with lack of randomization and blinding are susceptible to unmeasured covariates. Overall, we could not detect any relevant covariates, but further studies are needed to prove our results. A total of 34 patients including mainly patients with high risk of bleeding were analyzed. Due to this limited number, our study might be underpowered to prove a relation between infrequent risk factors and adverse events. In addition, it should be noted that all PDTs have been carried out by experienced interventionalists, so any learning curve effects and potential impact of operator skills were not considered in this study. Finally, for patients receiving therapeutic heparin infusions, the heparin was held for 4 hours before and 4 hours after which should substantially reduce the bleeding risk from this agent. Consequently, the risk of PDT cannot be evaluated for patients where heparin or another anticoagulant (e.g., bivalirudin) cannot be discontinued for this duration.

CONCLUSIONS

In summary, based on our analysis of 34 patients including mainly patients with high risk of bleeding, we show here that bronchoscopy-guided PDT according to Ciaglia technique is a safe and low-complication procedure for airway management in cardiac ICU patients. Even in the subpopulation on triple therapy with DAPT and therapeutic anticoagulation, it can be safely performed and this condition may not be regarded as a general contraindication for PDT. Furthermore, based on our findings, PDT may also be performed safely in obese patients and obesity should not be regarded as a general contraindication for PDT. In summary, this study demonstrates that PDT may be a safe procedure in cardiac ICU patients with risk factors such as DAPT, anticoagulation, or obesity.

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